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(71) Applicant: ADVANCED CARDIOVASCULAR SYSTEMS, INC. [US/US]; 3200 Lakeside Drive, Santa Clara, CA 95054-2807 (US).

(72) Inventors: FOREMAN, Philip, C.; 5642 Bergamo Court, San Jose, CA 95118 (US). LIMON, Timothy, A.; 10354 Byrne Avenue, Cupertino, CA 95014 (US). SAUNDERS, Richard, J.; 596 Marlin Court, Redwood City, CA 94065 (US). SINGH, Sushila; 5812 Civic Terrace Avenue, Newark, CA 94560 (US). SVENSSON, Bjorn, G.; 398 Cascades Court, Morgan Hill, CA 95037 (US). TRAN, Anh; 676 San Juan Drive, #10, Sunnyvale, CA 94086 (US).

(74) Agents: NAGY, John, S. et al.; Fulwider Patton Lee & Utecht, LLP, Howard Hughes Center, 10th floor, 6060 Center Drive, Los Angeles, CA 90045 (US).

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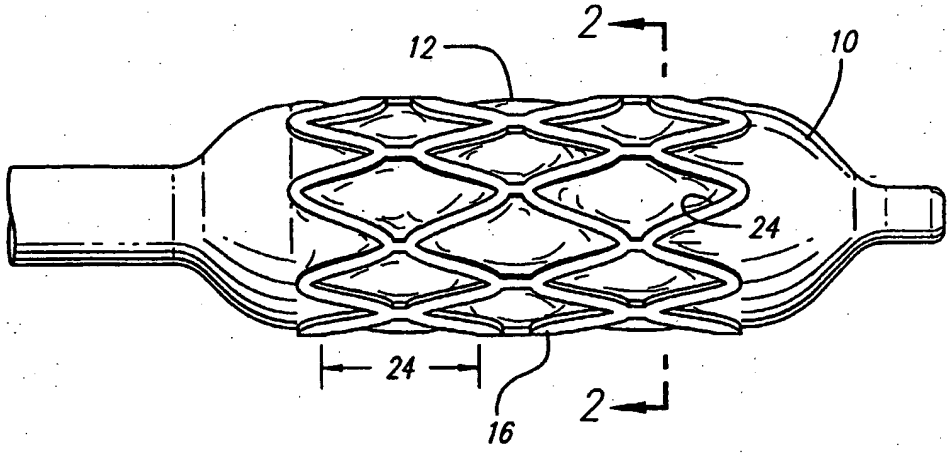
(54) Title: SYSTEM FOR REMOVABLY SECURING A STENT ON A CATHETER ASSEMBLY AND METHOD OF USE



(57) Abstract: The invention is directed to a system for removably securing a stent to the expandable member of a catheter assembly. The expandable member is deformed after the stent has been crimped onto the expandable member. Local deformations are formed in the expandable member and extend into gaps in the stent lattice structure so the stent is removably secured relative to the expandable member. Used with a stent delivery system this invention is inserted into a body lumen such as a coronary artery. The stent is retained in place while advancing the system through tortous coronary arteries, for example. The stent is implanted in the desired location in the artery by inflating the expandable member and thereby expanding the stent into the artery. The stent is released from the system by deflating the expandable member and withdrawing the catheter assembly from the patient.

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SYSTEM FOR REMOVABLY SECURING A STENT ON A CATHETER ASSEMBLY AND METHOD OF USE

BACKGROUND OF THE INVENTION

This invention relates to devices for the treatment of heart disease and particularly to endo-arterial prostheses, which are commonly called stents. More particularly, the invention relates to catheter assemblies for removably securing the stent to the catheter during delivery through a body lumen.

Several interventional treatment modalities are presently used for heart disease including balloon and laser angioplasty, atherectomy and by-pass surgery. In typical balloon angioplasty procedures, a guiding catheter having a performed distal tip is percutaneously introduced through the femoral artery into the cardiovascular system of a patient in a conventional Seldinger technique and advanced within the cardiovascular system until the distal tip of the guiding catheter is seated in the ostium. A guidewire is positioned within an inner lumen of a dilatation catheter and then both are advanced through the guiding catheter to the distal end thereof. The guidewire is first advanced out of the distal end of the guiding catheter into the patient's coronary vasculature until the distal end of the guidewire crosses a lesion to be dilated, then the dilatation catheter having an inflatable balloon on the distal portion thereof is advanced into the patient's coronary anatomy over the previously introduced guidewire until the balloon of the dilatation catheter is properly positioned across the lesion. Once in position across the lesion, the balloon, which is made of relatively inelastic materials, is inflated to a predetermined size with radiopaque liquid at relatively high pressure (e.g., greater than 4 atmospheres) to compress the plaque of the lesion against the inside of the artery wall and to otherwise expand the inner lumen of the artery. The balloon is then deflated so that blood flow can be resumed through the dilated artery and the dilatation catheter can be removed therefrom. Further details of dilatation catheters, guidewires, and devices associated therewith for angioplasty procedures can be found in U.S. Pat. No. 4,323,071 (Simpson-Robert); U.S. Pat. No. 4,439,185

(Lindquist); U.S. Pat. No. 4,516,972 (Samson); U.S. Pat. No. 4,538,622 (Samson, et al.); U.S. Pat. No. 4,554,929 (Samson, et al.); U.S. Pat. No. 4,616,652 (Simpson); U.S. Pat. No. 4,638,805 (Powell); U.S. Pat. No. 4,748,982 (Horzewski, et al.); U.S. Pat. No. 5,507,768 (Lau, et al.); U.S. Pat. No. 5,451,233 (Yock); and U.S. Pat. No. 5,458,651 (Klemm, et al.), which are hereby incorporated herein in their entirety by reference thereto.

One problem which can occur during balloon angioplasty procedures is the formation of intimal flaps which can collapse and occlude the artery when the balloon is deflated at the end of the angioplasty procedure. Another problem characteristic of balloon angioplasty procedures is the large number of patients which are subject to restenosis in the treated artery. In the case of restenosis, the treated artery may again be subjected to balloon angioplasty or to other treatments such as by-pass surgery, if additional balloon angioplasty procedures are not warranted. However, in the event of a partial or total occlusion of a coronary artery by the collapse of a dissected arterial lining after the balloon is deflated, the patient may require immediate medical attention, particularly in the coronary arteries.

A focus of recent development work in the treatment of heart disease has been directed to endoprosthetic devices called stents. Stents are generally cylindrically shaped intravascular devices which are placed within an artery to hold it open. The device can be used to reduce the likelihood of restenosis and to maintain the patency of a blood vessel immediately after intravascular treatments. In some circumstances, they can also be used as the primary treatment device where they are expanded to dilate a stenosis and then left in place.

One method and system developed for delivering stents to desired locations within the patient's body lumen involves crimping a stent about an expandable member, such as a balloon on the distal end of a catheter, advancing the catheter through the patient's vascular system until the stent is in the desired location within a blood vessel, and then inflating the expandable member on the catheter to expand the stent within the blood vessel. The expandable member is then deflated and

the catheter withdrawn, leaving the expanded stent within the blood vessel, holding open the passageway thereof.

However, retaining the position of the stent in the proper location on the expandable member while advancing the catheter through the body lumen has been found to be difficult. If the stent is dislodged from or moved relative to the expandable member the system will not correctly deliver the stent into the body lumen. This would require repeating the procedure. This delays insertion of the stent into the body lumen which may adversely affect the patient's health.

Different methods have been attempted to maintain the position of the stent on the expandable member. One such method involves a protective sheath surrounding the catheter and stent assembly, the sheath being retracted prior to inflation of the expandable member. The use of the sheath, however, increases the profile of the catheter assembly which must traverse narrow vessels. It would be an improvement to use a technique which does not increase the overall profile of the catheter assembly.

Another method has been to remove the friction reducing coating on the expandable member in the location of the stent thereby allowing the catheter assembly's pre-coated surface to hold the stent in frictional contact. This method has not proven satisfactory in maintaining the stent in the desired location.

What has been needed and heretofore unavailable is a satisfactory means of maintaining a stent in a desired location on a stent delivery system without increasing the overall profile of the catheter assembly. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The invention is directed to a stent delivery system for removably securing a stent onto an expandable member. Securing the stent is accomplished by deforming the expandable member beneath the stent so that the outer surface of the

expandable member bulges outwardly into the gaps in the stent. The resultant interference between the deformations and the stent prevents movement of the stent relative to the unexpanded expandable member.

Stent delivery systems are typically composed of an elongated inner tubular member with an expandable member attached adjacent to the inner tubular member distal end. The stent is located about the expandable member, so that the two can be expanded together. The present invention includes deforming the expandable member such that it maintains the stent in place during insertion into the body lumen. The invention can be used with the common configurations of stent delivery systems including over-the-wire (OTW) intravascular catheters and rapid exchange (Rx) or monorail intravascular catheters, also including perfusion-type catheters.

The local deformations can be formed in the expandable member by forcing an expansion fluid into the interior of the expandable member while the stent is crimped thereon. In this manner the expandable member partially inflates into the gaps in the stent. To restrain the expandable member from expanding during deformation of the expandable member an inelastic sheath can be placed about the stent. The inelastic sheath allows the internal pressures in the expandable member to exceed the levels which would otherwise expand the expandable stent. A further improvement is to heat the expandable member while deformed, to a sufficient temperature and for a sufficient duration to permanently deform the expandable member to form bulges which fill the gaps (voids) in the stent.

The invention results in a simplified method of delivering the stent into the body lumen. The catheter assembly is inserted into the body lumen without further steps being taken to secure the stent. The expandable member is inflated at the desired location thereby expanding and implanting the stent at the desired location within the body lumen. When the expandable member is then deflated the stent is released and the remainder of the catheter assembly may be withdrawn leaving the stent permanently implanted within the body lumen.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts a partial longitudinal plan view of an expandable member and stent assembly depicting the invention.

FIG. 2 depicts a cross-sectional view along lines 2-2 of FIG. 1.

FIG. 3 depicts a partial longitudinal plan view of an expandable member and stent assembly prior to forming bulges in the expandable member.

FIG. 4 depicts a partial longitudinal plan view of the expandable member and stent assembly partially covered by the retaining sheath.

FIG. 5 depicts a partial cross-sectional view of the stent delivery system within a body lumen.

FIG. 6 depicts a partial cross-sectional view of the stent delivery system whereby the expandable member has expanded the stent.

FIG. 7 is a plan view depicting an implanted stent in a body lumen.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1 and 2 illustrate a catheter assembly containing a system for removably securing a stent which embodies, by way a example, the features of the

invention. Generally, the catheter assembly includes expandable member 10 having local deformations 12 on outer surface 14 of the expandable member. An expandable stent 16 is tightly crimped about the expandable member and is removablly secured thereon due to interference between the stent and the local deformations.

Stent delivery systems typically include expandable members 10, generally in the form of inflatable dilatation balloons. The expandable member is formed as an elongated cylinder defining an outer surface 14, an inner surface 18 and an interior space 20. The interior space is adapted to receive an inflation fluid 22 under substantial pressure which inflates the expandable member.

Expandable stents 16 have a lattice configuration defined by a series of gaps 17 within the stent body. Stents typically are mounted on a catheter by crimping them about the expandable member of the catheter so that the expandable member can, during inflation, expand the radially outwardly stent. Local deformation 12 of the expandable member extends outwardly from outer surface 18 of the expandable member into gaps 17. The resultant interference between the local deformations and the gaps in the stent act to prevent relative motion between the stent and the expandable member.

FIGS. 3 and 4 illustrate, by way of example, a method of removably securing an expandable member onto a stent delivery system. The preferred method involves deforming expandable member 10 with expandable stent 16 crimped onto outer surface 14 of the expandable member.

One preferred method of deforming expandable member 10 is to partially inflate the expandable member by injecting inflation fluid 22 under substantial pressure into interior space 20 of the expandable member. The expandable member is prevented from venting the expansion fluid by enclosing one end (not shown). In this manner the expandable member forms local deformations 12 into gaps 17 which secure the stent by increasing the interference between outer surface 14 of the expandable member and the expandable stent.

In another preferred process of the invention, as shown in FIG. 4, inelastic sheath 26 is placed over expandable stent 16 which is tightly crimped onto expandable member 10 before the expandable member is deformed. The sheath is placed so that it entirely encompasses the expandable stent and acts to prevent the expandable stent from expanding while the expandable member is deformed. Deformation of the balloon to form local deformations 12 to fill gaps 24 in the stent lattice is enhanced by use of the sheaths. Placing the sheath over the stent allows the pressure of the inflation fluid 24 in interior space 20 of the expandable member to exceed the levels which would otherwise cause the stent to expand. The local deformations form in the stent gaps as the expandable member starts to expand but the stent cannot expand because it is restrained by the sheath. Increased pressure ensures that greater deformations will occur in the expandable member while the expandale stent remains in the unexpanded condition. Once the deformation process is complete, the inelastic sheath is removed from the expandable stent.

Another preferred process is to heat expandable member 10 while it is being deformed. Heat 28 is applied to the expandable member to a sufficient temperature and for a sufficient duration to permanently deform the expandable member. The heating step preferably occurs while interior space 20 of the expandable member is subjected to sufficient pressures to form the desired local deformations 12 in the expandable member. This step ensures the expandable member will retain the desired deformations after pressure has been removed from the interior space.

The preferred process of forming local deformations 14 includes all the steps mentioned. First, inelastic sheath 26 is placed over expandable stent 16, entirely encompassing the stent and preventing it from expanding. Then inflation fluid 22 is injected into interior space 20 of the expandable member partially inflating the expandable member and forming local deformations 12 in the outer surface of the expandable member which extend outwardly into gaps 24 in the stent. The expandable member is then heated 28 to a sufficient temperature and for a sufficient time to make

the local deformations permanent. The inflation fluid is then withdrawn from the interior space. The inelastic sheath is then removed from around the expandable stent.

These inventive processes produce an assembly of an expandable stent and deformed expandable member. The improved assembly is an efficient means to removably secure the stent onto the expandable member for delivery and insertion into a body lumen.

When combined with a stent delivery system the invention results in an improved process for delivering and implanting a stent to a desired location within a body lumen. Figures 5 through 7 illustrate, by way of example, a method of delivering and implanting a stent mounted in accordance with the invention. While the drawing figures illustrate a rapid exchange (Rx) intravascular catheter 30, another embodiment of the invention includes an over-the-wire (OTW) intravascular catheter (not shown). The figures also illustrate a typical situation in which the invention is used after an intravascular procedure has created a dissection in the arterial lining to such an extent that the lining needs support to prevent it from collapsing into the arterial passage way and preventing sufficient blood flow through the vessel. In these situations, the stent of the invention can be delivered to and implanted into the location requiring support without the use of further means to secure the stent.

The catheter assembly, with the stent removably secured on the expandable member, is inserted into a body lumen 32, such as a coronary artery, along a guidewire 34 which is already in position distal to the desired location 36 requiring support. As illustrated in FIG. 6, the expandable member is expanded thereby expanding the expandable stent 16 and implanting it within the body lumen. This may be accomplished, for example, by injecting inflation fluid 22 into interior space 20 of the expandable member under substantial pressure. Since local deformations 12 extend into stent gaps 24, the stent remains stationary relative to the expandable member until the expandable member is inflated. After the stent is expanded, the expandable member is then deflated. The expandable stent remains implanted in the desired location of the body lumen. The remainder of the catheter assembly, with the

expandable stent no longer in contact with the expandable member, is then withdrawn from the body lumen.

The dimensions of the intravascular catheter will generally follow the dimensions of intravascular catheters used in angioplasty procedures in the same arterial location. Typically, the length of a catheter for use in the coronary arteries is about 150 cm, the outer diameter of the catheter shaft is about 0.035 inch (0.89 mm), the length of the balloon is typically about 2 cm and the inflated diameter about 1 to about 8 mm depending upon the application. Catheter dimensions for peripheral use will vary and is known in the art.

The materials of construction of the catheter and expandable member may be selected from those used in conventional balloon angioplasty catheters, such as those described in the patents incorporated by reference.

While the present invention has been described herein in terms of delivering an expandable stent to a desired location within a patient's blood vessel, the delivery system can also be employed to deliver stents to locations within other body lumens so that the stents can be expanded to maintain the patency of those body lumens. Various changes and improvement may also be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. A catheter assembly for removably securing an expandable stent during stent delivery and implantation within a body lumen, comprising:

a catheter having an expandable member configured as an elongated cylinder defining an interior space and having an outer surface;

a plurality of outwardly bulging local deformations on the outer surface of the expandable member; and

an expandable stent tightly crimped onto the outer surface of the expandable member and local deformations.

2. The catheter assembly of claim 1, wherein the expandable stent comprises a lattice configuration defining gaps within the stent, the expandable stent being tightly crimped about the outer surface of the expandable member so that the local deformations extend into the gaps in the expandable stent.

3. The catheter assembly of claim 1, wherein the expandable member comprises an inflatable dilatation balloon.

4. The catheter assembly of claim 1, wherein the catheter includes an over-the-wire-type intravascular catheter.

5. The catheter assembly of claim 1, wherin the catheter includes a rapid-exchange-type intravascular catheter.

6. A method of removably securing an expandable stent on a catheter delivery system, the method comprising:

providing a catheter having an expandable member shaped as an elongated cylinder defining an inner surface, an interior space, and an outer surface;

providing an expandable stent aligned about the expandable member and crimped thereon, the expandable stent having a lattice configuration defining gaps in the stent; and

deforming the expandable member so that the expandable stent is restrained from moving relative to the expandable member.

7. The method of claim 6, wherein deforming the expandable member includes injecting an inflation fluid into the interior space of the expandable member under substantial pressure, thereby partially inflating the expandable member and producing local deformations on the outer surface therof.

8. The method of claim 6, further comprising:

heating the expandable member after deforming the expandable member so that the expandable member is permanently deformed.

9. The method of claim 6, further comprising:

positioning an inelastic sheath about the expandable stent before deforming the expandable member, so that the expandable stent is restrained from expanding while the expandable member is deformed; and

removing the inelastic sheath after the expandable member is deformed.

10. A method of delivering and implanting an expandable stent into a desired location within a body lumen, the method comprising:

providing a catheter assembly comprising:

a catheter having an expandable member shaped as an elongated cylinder defining an inner surface and an outer surface; local deformations in the expandable member extending outwardly from the outer surface; an expandable stent crimped about the expandable member and removably secured to the expandable member due to the interference between the expandable stent and the local deformations;

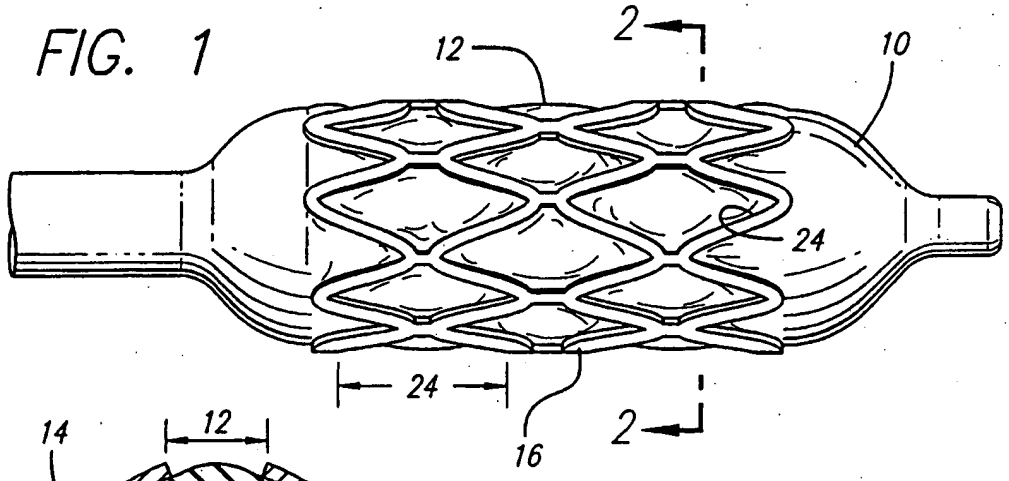
advancing the catheter assembly though the body lumen to the desired location;

inflating the expandable member thereby expanding and implanting the stent at the desired location;

deflating the expandable member so that the expandable stent is no longer in contact with the catheter assembly; and

withdrawing the catheter assembly from the body lumen.

FIG. 1



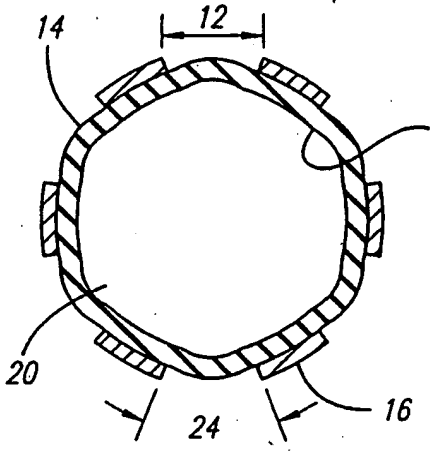


FIG. 2

FIG. 3

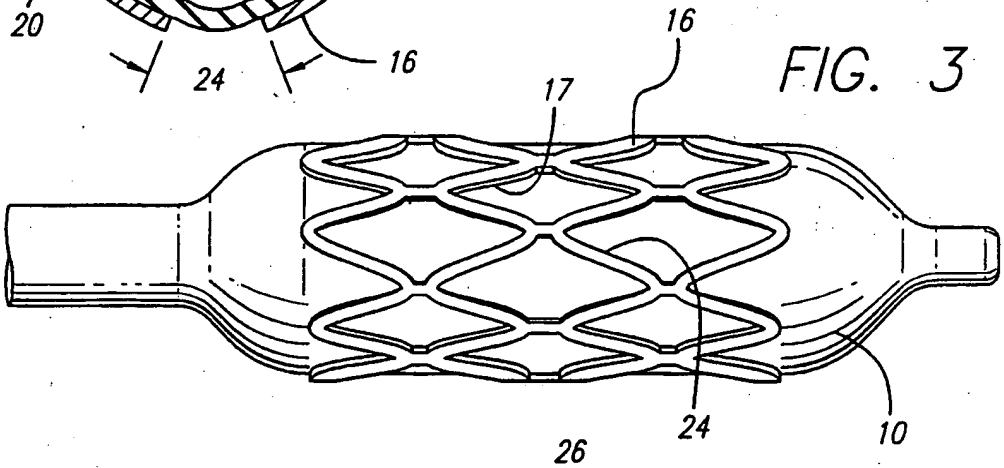


FIG. 4

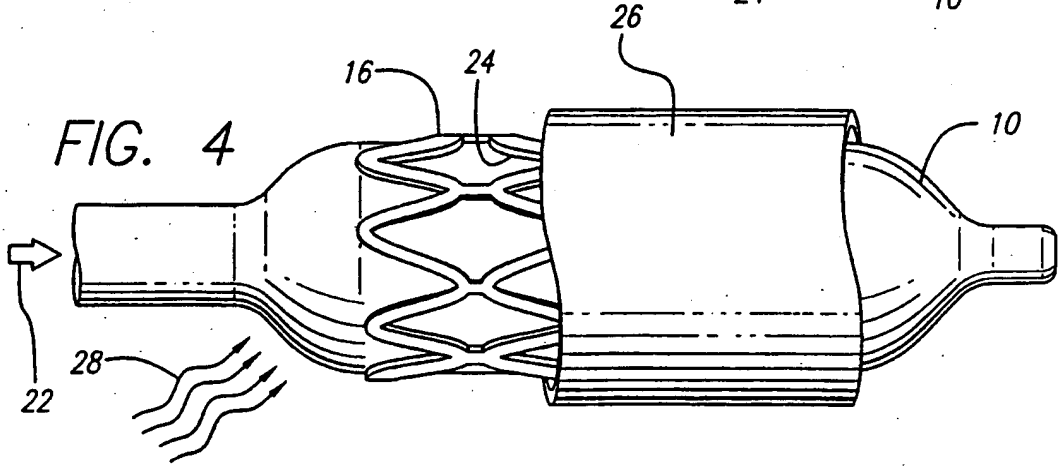


FIG. 5

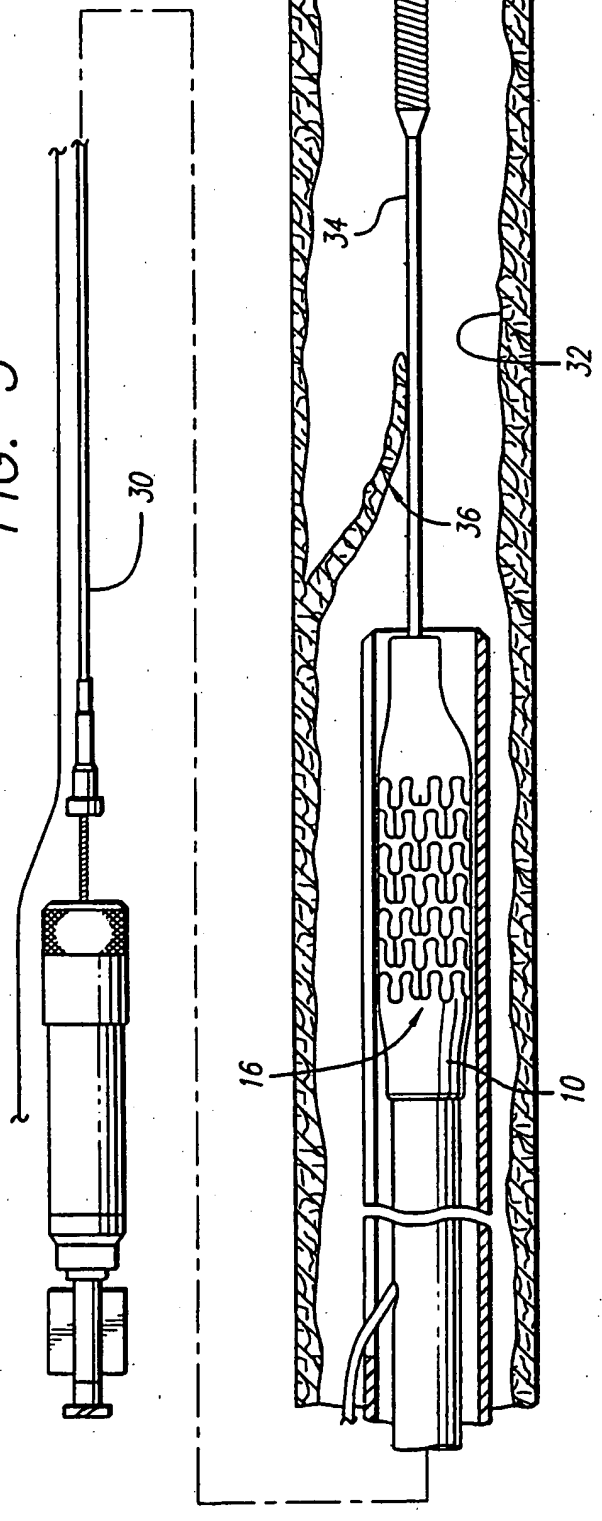


FIG. 7

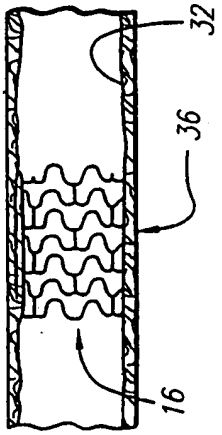
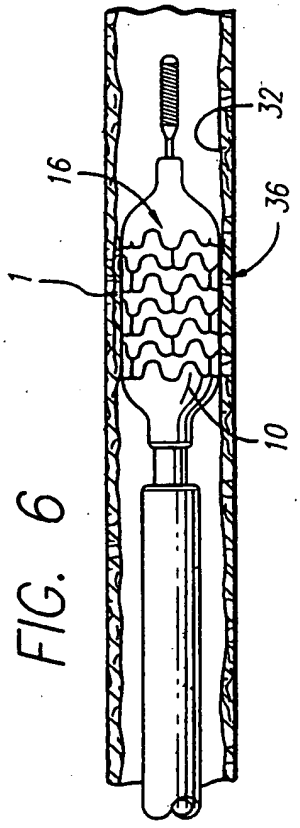


FIG. 6



INTERNATIONAL SEARCH REPORT

Inte. onal Application No
PCT/US 00/24584

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 976 155 A (SVENSSON BJOERN G ET AL) 22 June 1999 (1999-06-22) column 1, line 5 - line 15; figures column 5, line 21 -column 6, line 63	1-3,6,8, 9
X	WO 96 12517 A (APPLIED VASCULAR ENG INC) 2 May 1996 (1996-05-02) page 5, line 31 -page 6, line 13; figures	1,3,6-9
X	EP 0 834 293 A (CORDIS EUROP) 8 April 1998 (1998-04-08) column 2, line 25 -column 3, line 49; figures	1-3,6,8
X	WO 99 10037 A (SOLAR RONALD J) 4 March 1999 (1999-03-04) page 6, line 6 -page 11, line 3; figures	1,3-5
A		6

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ational Application No
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